DRES
(B. Steinwand)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 9/25/96

SUBJECT: ID#96CA0038. SECTION 18 EXEMPTION FOR USE OF MYCLOBUTANIL ON CUCURBITS IN THE STATE OF CALIFORNIA.

DP Barcode: D228683 Caswell: 723K
Trade Name: Rally 40W Chem#: 128857
Reg#: 707-215 40 CFR: 180.443
Class: Fungicide

TO: David Deegan, PM Team 41
ERMUS/RSB/RD (7505W)

FROM: Steven Knizner, Charles Lewis,
William Dykstra, Donna Davis
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)

THRU: Michael S. Metzger, Acting Chief
RCAB/HED (7509C)

INTRODUCTION

The California Department of Pesticide Regulation is proposing an emergency exemption for the use of myclobutanil on cucurbits for control of powdery mildew (*Sphacrotheca fuliginea*). A Section 18 Crisis Exemption was issued by California on July 26, 1996, for use of myclobutanil on watermelons grown in Fresno, Merced, San Joaquin, Stanislaus, Sutter, Yolo and Yuba Counties only. The current emergency exemption adds Colusa and Kern counties and expands the use to permit application to all cucurbits.

RECOMMENDATION

To be in compliance with WPS, the product label must be modified to require a 48-hour REI (not 24 hours as is on the current label). Provided the label is modified, occupational exposure estimates do not exceed HED's level of concern.

Dietary risk estimates do not exceed HED's level of concern and this Section 18 use should not pose an unacceptable dietary risk to infants and children. Therefore, HED has no objection to the issuance of this Section 18 exemption for the use of myclobutanil on cucurbits in the State of California. A time-limited tolerance for residues of myclobutanil plus its alcohol metabolites (free and bound) should be established for cucurbits at 0.3 ppm to support this Section 18 crisis exemption.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

   a) Short-Term Risk. For short-term dermal margin of exposure (MOE) calculations, the TES Committee (7/12/94) recommended use of the systemic NOEL of 100 mg/kg/day from the 21-day dermal toxicity study in rats (MRID# 00266080). This dose level was the highest tested in the study. The TES Committee did not identify an inhalation endpoint.

   b) Intermediate-Term Risk. For intermediate-term MOE calculations, the TES Committee (7/12/94) recommended use of the NOEL of 10 mg/kg/day from the 2-generation rat reproduction study (MRID#s 00143766, 00149581). At the LEL of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in number of stillborns, and atrophy of the prostate and testes.

   c) Chronic Risk. For chronic MOE calculations, the TES Committee did not recommend a study. There is no chronic exposure scenario associated with this §18 action.

   d) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee (12/4/95) as a Group E chemical - "no evidence of carcinogenicity for humans".

   e) Dermal Penetration. For short-term MOEs, a dermal toxicity study was used, and dermal penetration data were not applied. For intermediate-term MOEs, 100% dermal penetration (default value) was used.

2. Dietary Endpoint Selection

   a) Acute Risk. The TES Committee has not identified an acute dietary toxicological endpoint.

   b) Chronic Risk. The RfD of 0.025 mg/kg/day was established by the RfD/Peer Review Committee (12/4/95)

based on the chronic feeding study in rats (MRID#s 00149582, 00165247) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100 based on testicular atrophy at the LEL of 9.9 mg/kg/day.

c) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee as a Group E chemical - "no evidence of carcinogenicity for humans".

d) Infants and Children

i) Developmental Studies

Rat - From the rat developmental study (MRID #00141672), the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (pup) NOEL was 93.8 mg/kg/day, based on increased incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

Rabbit - From the rabbit developmental study (MRID #00164971), the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (pup) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LEL of 200 mg/kg/day.

ii) Reproduction Studies

Rat - From the rat reproduction study, the maternal (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LEL of 50 mg/kg/day. The reproductive (parental) NOEL was 10 mg/kg/day, based on increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

Occupational Exposure

1. Acute data for this formulation are available to PIRAT. Based on the toxicity categories in the Tox Oneliners, the work clothing and personal protective equipment (PPE) appearing on the label are in compliance with the Worker Protection Standard (WPS). The label cited in the submission (Rally 40W, Agricultural Fungicide, in Water Soluble Pouches, EPA Reg. No. 707-215-AA) requires applicators and other handlers to wear long-sleeved shirt,

long pants, waterproof gloves, shoes plus socks, protective eyewear, and chemical-resistant headgear for overhead exposure.

2. Acute toxicological data for the technical are available. According to the Tox Oneliners, myclobutanil is a category I for primary eye irritation; category III for acute oral and dermal LD50; category IV for primary dermal irritation and acute oral LD50. Based on these values, the restricted entry interval (REI) should be 48 hours to be in compliance with the WPS. However, the label lists an REI of 24 hours. **RD should insure that the appropriate REI statement appears on the label.**

3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. PIRAT has calculated the estimates of exposure with mixer/loaders and applicators wearing a single layer of clothing plus gloves. Insufficient data are available in PHED for water soluble pouches. The mixer/loader estimates of exposure are based on wettable powders, open pour. Consequently, **the calculated MOEs should be considered very conservative.** In addition, the TES Committee did not identify inhalation exposure as either a short or intermediate-term risk. As a result, estimates of exposure do not include the inhalation route. However, based on the use of water soluble pouches, inhalation exposure should be low.

Dietary Exposure

1. The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).

2. An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID# 408033-02) is available to enforce the tolerance expression. Quantitation is by GLC using an N/P detector for myclobutanil and an EC detector for residues measured as the alcohol metabolite is available A copy is on file in PP#4E4302.

3. Combined residues of myclobutanil plus its alcohol metabolite in cucurbits are **not expected to exceed 0.3 ppm** as a result of this Section 18 use. A time-limited tolerance should be established at this level.

4. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

5. Dietary exposure estimates (DRES) for myclobutanil are summarized in the Attachment.

a) Acute Dietary Risk. This risk assessment is not required as the TES Committee did not identify any acute dietary risk endpoints.

b) Chronic Dietary Risk. After refinement using percent crop treated for some commodities having existing tolerances, and incorporating this Section 18 use, the resulting Anticipated Residue Contributions are equivalent to the following percentages of the RfD:

U.S Population (48 states)	13.5%
Nursing Infants	25.0%
Non-Nursing Infants (<1 year old)	73.1%
Children (1-6 years old)	38.7%
Children (7-12 years old)	21.8%

c) Dietary Cancer Risk. This risk assessment is not required as the RfD Committee has classified myclobutanil as a Group "E" carcinogen (no evidence of carcinogenicity for humans).

d) Anticipated Residues. Percent crop treated data were used for some of the existing myclobutanil tolerances in the DRES analysis (stone fruits, pome fruits, grapes, and cottonseed). Use of this refinement to residue levels along with tolerance level residues on cucurbits resulting from the proposed Section 18 use does not result in anticipated residue contributions (ARCs) that exceed the RfD for the US general population or any of the 22 subgroups analyzed. Therefore, there is no need for additional anticipated residue assessment refinement at this time.

Aggregate Exposure

1) Water - Review of terrestrial field dissipation data by the Environmental Fate and Effects Division indicates that myclobutanil did not leach into groundwater in either sandy loam or coastal soil. There is no established Maximum Concentration Level for residues of myclobutanil in drinking water. No drinking water health advisories have been issued for myclobutanil. The "Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil. Based on the available data, PIRAT does not anticipate that there will be significant exposure to the general population from myclobutanil residues in drinking water.

2) Non-occupational Exposure - Myclobutanil is registered for outdoor residential use on annuals and perennials, turf, shrubs and trees, and african violets (indoor). Concerning acute risks from non-occupational exposure, PIRAT does not

consider it likely that an individual would experience an acute dietary and acute residential exposure event at the same time. For short-term risks, PIRAT acknowledges that there may be short-term residential exposure scenarios, however no acceptable reliable data to assess these potential risks are available at this time. For chronic risks, PIRAT does not anticipate a chronic exposure scenario resulting from residential uses.

Cumulative Effects

At this time, PIRAT concludes that insufficient information is available to consider cumulative effects of myclobutanil and other substances that may have a common mode of toxicity. For purposes of this Section 18 only, PIRAT is considering only the potential risks of myclobutanil in its aggregate exposure.

Determination of Safety for Infants and Children

Based on current toxicological data requirements, the database for myclobutanil relative to pre- and post-natal toxicity is complete. PIRAT notes that there is approximately a 25-fold difference between the developmental NOEL of 60 mg/kg/day from the rabbit developmental toxicity study and the NOEL of 2.5 mg/kg/day from the chronic rat feeding study which was the basis of the RfD. It is further noted that in both the rabbit and rat developmental toxicity studies, the developmental NOEL and maternal NOEL are the same (60 mg/kg/day for the rabbit and 93.8 mg/kg/day for the rat). In the rat reproduction study, the maternal NOEL (2.5 mg/kg/day) was four times lower than the developmental (pup) and reproductive NOELs (10 mg/kg/day). These studies indicate that there does not appear to be additional sensitivity for infants and children in the absence of maternal toxicity.

The ARC value for the most highly exposed infant and children subgroup (non-nursing infants <1 year old) occupies 73.1% of the RfD. However, this calculation also assumes 100% crop treated (except for stone fruits, pome fruits, grapes, and cottonseed) and uses tolerance level residues for all commodities. Refinement of the dietary risk assessment by using additional percent crop treated data and anticipated residue data would reduce dietary exposure. Therefore, this risk assessment, although moderately refined, remains an over-estimate of dietary risk.

If an additional uncertainty factor be deemed appropriate for infants and children, when considered in conjunction with a refined exposure estimate, it is unlikely that the dietary risk will exceed 100 percent of the RfD for any

population sub-group. Therefore, HED concludes that this Section 18 use should not pose an unacceptable risk to infants and children.

SUPPLEMENTAL INFORMATION

Occupational Exposure

Table 1. Occupational Exposure Assumptions

PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Best Available Surrogate Exposure Table (BASET,5/29/96)	Mixer/Loader (wettable powder, open bag, single layer clothing plus gloves): Dermal = 160.0 µg/lb ai handled, Inhalation = 43.4 µg/lb ai handled
	Applicator (groundboom, open cab, single layer clothing plus gloves): Dermal = 14.0 µg/lb ai applied, Inhalation = 0.7 µg/lb ai applied
	Applicator - (aerial, liquid formulations, enclosed cockpits, single layer clothing, no gloves): Dermal = 5.0 µg/lb ai applied, Inhalation = 0.068 µg/lb ai applied
Percent Absorption	Dermal: NA (based on dermal toxicity study) Inhalation: 100 % (default value)
Application Type	Ground and aerial
Minimum Finish Spray	Ground: 20 gal/A Air: 10 gal/A
Maximum Application Rate	0.1 lb ai/A
Maximum Applications Per Year	6
Duration of Occupational Exposure	Intermediate (one week to several months)
Acres Treated/Day (Y. NG,BEAD)	Ground: 89 acres Air: 228 acres
Average Farm Size (1992 Ag Census)	Based on Fresno county, CA 175 acres (cantaloupes)
Worker Weight	70 kg (based on Tox endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2 Air: 10

Table 2. Occupational Exposure and Risk Assessment[a]			
Worker	Average Daily Dermal Dose[b] (ug/kg/day)	Short-Term MOE[c]	Intermediate-Term MOE[d]
Ground Mixer/Loader	20.3	4,900	500
Ground Applicator	1.8	56,000	5,600
Aerial Mixer/Loader	52.1	1,900	190
Aerial Applicator	1.6	63,000	6,300

[a] MOEs are expressed to two significant figures.
[b] Average Daily Dose (ADD) = PHED dermal unit exposure x application rate x acres treated/day ÷ kg body weight.
[c] Short-Term Occupational Exposure MOE = NOEL/ADD (where NOEL = 100 mg/kg/day).
[d] Intermediate Occupational Exposure MOE = NOEL/ADD (where NOEL = 10 mg/kg/day).

Dietary Exposure

Table 3. Residue Considerations Summary Table		
PARAMETER	PROPOSED USE	COMPARISON RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W (EPA Reg. No. 707-215) (packaged in water-soluble pouches)	Rally 40W (EPA Reg. No. 707-215) (packaged in water-soluble pouches)
CROP	Cucurbits	Cantaloupe
TYPE APPLICATION	Foliar, by ground (20 gpa) or air (10 gpa). Do not apply by chemigation.	Ground - full coverage foliar spray
# APPLICATIONS	≤ 6	6-7
TIMING	Begin at first sign of disease and continue on a 7-10 day schedule. Applications may be made up to day of harvest.	Began with onset of disease and was repeated at 6-12 day intervals (CA; MD not specified) until 0-7 days before harvest.
RATE/APPLICATION	0.1 lb ai/A	0.063 lb ai/A (MD); 0.063/0.125 lb ai/A (CA)
RATE/SEASON	0.6 lb ai/A	0.441 lb ai/A (MD); 0.378/0.75 lb ai/A (CA)

Table 3. Residue Considerations Summary Table		
PARAMETER	**PROPOSED USE**	**COMPARISON RESIDUE DATA**
MAXIMUM RESIDUE	N/A	**0.19 ppm.** Cantaloupe (7 x 0.063 lb ai/A = 0.441 lb ai/A, 3/4X label seasonal max), 0- & 5-day PHIs, MD, 86-0369). 0.11 ppm. Squash
RESTRICTIONS	One day PHI. For use in Colusa, Fresno, Kern, Merced, San Joaquin, Stanislaus, Sutter, Yolo and Yuba Counties only. Follow §3 registered label's rotational crop restrictions.	Do not exceed 1.5 lbs (0.6 lb ai)/A/crop. Follow label rotational crop restrictions.
RESIDUE DATA SOURCE	N/A	MRID# 410855-01 (MD/cantaloupes/86-0369) MRID# 421890-01 (CA/cantaloupes/90-0128 and 90-0123) (Both reviewed re PP#s 9G3765 and 2F4155)
PERFORMING LAB	N/A	Rohm and Haas Co., Spring House, PA

Attachments: Chronic DRES Analysis (9/23/96)

cc with Attachments: Knizner, PIRAT, DRES (B. Steinwand)

cc without attachments: Lewis, Dykstra, Davis (PIRAT), Caswell File, TOX, CBTS (Sect 18), RCAB (P.Deschamp)

RDI:PIRAT:9/25/96

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.004003	0.005072	20.288844	4.274868	0.003375	13.50144
U.S. POPULATION - SPRING SEASON	0.003757	0.004780	19.118212	4.090196	0.003164	12.65484
U.S. POPULATION - SUMMER SEASON	0.004314	0.005480	21.919840	4.662064	0.003461	13.84490
U.S. POPULATION - FALL SEASON	0.004009	0.005058	20.231180	4.195328	0.003469	13.87750
U.S. POPULATION - WINTER SEASON	0.003935	0.004973	19.891168	4.149348	0.003407	13.62841
NORTHEAST REGION	0.004366	0.005426	21.704036	4.242004	0.003626	14.50531
NORTH CENTRAL REGION	0.004078	0.005064	20.257052	3.945340	0.003428	13.71237
SOUTHERN REGION	0.003235	0.004158	16.630620	3.692496	0.002813	11.25018
WESTERN REGION	0.004741	0.006193	24.773364	5.808688	0.003935	15.74097
HISPANICS	0.004674	0.006391	25.562344	6.866132	0.004060	16.24136
NON-HISPANIC WHITES	0.004078	0.005152	20.609144	4.298792	0.003417	13.66736
NON-HISPANIC BLACKS	0.003195	0.003863	15.453580	2.675348	0.002749	10.99673
NON-HISPANIC OTHERS	0.004125	0.005663	22.652896	6.151260	0.003663	14.65329
NURSING INFANTS (< 1 YEAR OLD)	0.009474	0.013918	55.670956	17.775732	0.006240	24.96001
NON-NURSING INFANTS (< 1 YEAR OLD)	0.024494	0.029747	118.986496	21.009292	0.018274	73.09516
FEMALES (13+ YEARS, PREGNANT)	0.002867	0.003481	13.922248	2.455128	0.002358	9.43224
FEMALES 13+ YEARS, NURSING	0.003678	0.004579	18.314848	3.601856	0.003102	12.40620
CHILDREN (1-6 YEARS OLD)	0.011227	0.014402	57.608356	12.701624	0.009674	38.69660
CHILDREN (7-12 YEARS OLD)	0.006287	0.007663	30.652300	5.506136	0.005450	21.79882
MALES (13-19 YEARS OLD)	0.003574	0.004294	17.174444	2.877168	0.003230	12.91943
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.002968	0.003597	14.389052	2.518640	0.002591	10.36222
MALES (20 YEARS AND OLDER)	0.002328	0.003017	12.069784	2.756308	0.001974	7.89600
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.002344	0.003067	12.268496	2.891520	0.001903	7.61157

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
01014AA	GRAPES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014DA	GRAPES-RAISINS	10 RAW-FRESH OR NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	21 COOKED-NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	22 COOKED-FRESH-BAKED	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014JA	GRAPES-JUICE	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
03001AA	ALMONDS	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	21 COOKED-NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		1.00	0.001000
04001AA	APPLES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	21 COOKED-NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	22 COOKED-FRESH-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04002AA	CRABAPPLES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
04003AA	PEARS-FRESH	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	31 COOKED-FRESH OR CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	51 COOKED-CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	21 COOKED-NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04004AA	QUINCES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F3954	P 2.000000	2.000000		1.00	0.020000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#		TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
05002JA	CHERRIES-JUICE	21 COOKED-NFS	2F4116	P	5.000000	5.000000		47.00	2.350000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	9F3811	P	2.000000	2.000000		21.00	0.420000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	9F3811	P	2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	21 COOKED-NFS	9F3811	P	2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	9F3811	P	2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	9F3811	P	2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	9F3811	P	2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	21 COOKED-NFS	9F3811	P	2.000000	2.000000		22.00	0.440000
05005AA	PLUMS-FRESH	10 RAW-FRESH OR NFS	1F3954	P	2.000000	2.000000		3.00	0.060000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P	2.000000	2.000000		3.00	0.060000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	1H5608	P	8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	1H5608	P	8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	1H5608	P	8.000000	8.000000C		3.00	0.240000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	1F3954	P	2.000000	2.000000		3.00	0.060000
05005JA	PRUNE-JUICE	62 COOKED-FRESH OR FROZEN-BAKED	1F3954	P	2.000000	2.000000		3.00	0.060000
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	2E04141	A	4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2E04141	A	4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2E04141	A	4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2E04141	A	4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2E04141	A	4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2E04141	A	4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	21 COOKED-NFS	2E04141	A	4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2E04141	A	4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2E04141	A	4.000000	0.800000		100.00	0.800000
10002AA	CANTALOUPES-UNSP	00 NOT SPECIFIED (NO CONSUMPTION)	96CA38	N	0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES-PULP	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES-PULP	21 COOKED-NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10003AA	CASABAS	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10004AA	CRENSHAWS	00 NOT SPECIFIED (NO CONSUMPTION)	96CA38	N	0.300000	0.300000		100.00	0.300000
10005AA	HONEYDEW MELONS	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10007AA	PERSION MELONS	00 NOT SPECIFIED (NO CONSUMPTION)	96CA38	N	0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	21 COOKED-NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	11 RAW-FRESH-PICKLED,CORNED,OR CURED	96CA38	N	0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	21 COOKED-NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	21 COOKED-NFS	96CA38	N	0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	22 COOKED-FRESH-BAKED	96CA38	N	0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	62 COOKED-FRESH OR FROZEN-BAKED	96CA38	N	0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	10 RAW-FRESH OR NFS	96CA38	N	0.300000	0.300000		100.00	0.300000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	MED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
10013AA	SQUASH-SUMMER	21 COOKED-NFS	96CA38	N 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	10 RAW-FRESH OR NFS	96CA38	N 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	21 COOKED-NFS	96CA38	N 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	31 COOKED-FRESH OR CANNED	96CA38	N 0.300000	0.300000		100.00	0.300000
10017AA	BITTER MELON	21 COOKED-NFS	96CA38	N 0.300000	0.300000		100.00	0.300000
10020AA	TOWELGOURD	00 NOT SPECIFIED (NO CONSUMPTION)	96CA38	N 0.300000	0.300000		100.00	0.300000
27003OA	COTTONSEED-OIL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
27003WA	COTTONSEED-MEAL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
43058AA	WINE AND SHERRY	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
43058AA	WINE AND SHERRY	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
50000DB	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001DA	BEEF-DRIED	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001KA	BEEF-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002BB	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000

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Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
53002FA	GOAT-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002KA	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002LA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005FA	SHEEP-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005MA	SHEEP-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53005MA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006BA	PORK-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006KA	PORK-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006LA	PORK-LIVER	21 COOKED-NFS	0F3876	P 1.000000	1.000000		100.00	1.000000
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53006MA	PORK-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.100000	0.100000		100.00	0.100000
55008BA	TURKEY-BYP	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MC	TURKEY-UNSPEC	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55013BA	POULTRY,OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55013LA	POULTRY,ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55013MA	POULTRY,OTHER	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000

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55014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	81 COOKED-FROZEN	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015BA	CHICKEN-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	53 COOKED-CANNED-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000

EMERGENCY EXEMPTION FOR **MYCLOBUTANIL** ON **CUCURBITS** AND FFDCA TOLERANCES

On [ ] 1996, EPA approved emergency exemptions under FIFRA section 18 for the state of California for use of myclobutanil on cucurbits in California to control powdery mildew (*Sphacrotheca fuliginea*).

RISK ASSESSMENT

Toxicological Profile

Chronic Effects: The RfD of 0.025 mg/kg/day was established by the Agency based on the chronic feeding study in rats with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. There was testicular atrophy at the LEL of 9.9 mg/kg/day.

Acute Toxicity: The Agency has not identified an acute dietary toxicological endpoint.

Carcinogenicity: Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified myclobutanil as Group E chemical - "no evidence of carcinogenicity for humans" - based on the results of carcinogenicity studies in two species. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment is not required.

Aggregate Exposure

For purposes of assessing the potential dietary exposure under these tolerances, EPA has estimated aggregate exposure based on the TMRC from the tolerance for myclobutanil on cucurbits at 0.3 ppm. The TMRC is obtained by multiplying the tolerance level residue for cucurbits by the consumption data, which estimate the amount of cucurbits and cucurbit products eaten by various population subgroups. There are no livestock feed items associated with cucurbits, so no additional livestock dietary burden will result from this Section 18 registration. Therefore, existing meat/milk/poultry tolerances are adequate.

Other established U.S. tolerances for myclobutanil are found in 40 CFR 180.443, and range from 0.05 ppm for milk to 5 ppm for cherries (sweet and sour). In conducting this exposure assessment, EPA has made conservative assumptions--100% of cucurbits will contain myclobutanil residues and those residues would be at the level of the tolerance. Percent crop treated data were used for some of the commodities with existing myclobutanil tolerances (stone fruits, pome fruits, grapes, and cottonseed). Thus, in making a safety determination for the subject Section 18 tolerances, EPA is taking into account this conservative exposure assessment.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Based on the available studies used in EPA's assessment of environmental risk, EPA does not anticipate exposure to residues of myclobutanil in drinking water. Review of terrestrial field dissipation data by the Agency indicates that myclobutanil did not leach into groundwater in either sandy loam or coastal soil. There is no established Maximum Concentration Level for residues of myclobutanil in drinking water. No drinking water health advisories have been issued for myclobutanil. The "Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil. Based on the available data, the Agency does not anticipate that there will be significant exposure to the general population from myclobutanil residues in drinking water.

Myclobutanil is registered for outdoor residential use on annuals and perennials, turf, shrubs and trees, and african violets (indoor). Concerning acute risks from non-occupational exposure, the Agency does not consider it likely that an individual would experience an acute dietary and acute residential exposure event at the same time. For short-term risks, EPA acknowledges that there may be short-term residential exposure scenarios, however no acceptable reliable data to assess these potential risks are available at this time. For chronic risks, the Agency does not anticipate a chronic exposure scenario resulting from residential uses.

EPA also considered the potential for cumulative effects of myclobutanil and other substances that have a common mode of toxicity. EPA concluded that consideration of a common mode of toxicity is not appropriate at this time. EPA does not have reliable information to indicate that toxic effects produced by myclobutanil would be cumulative with those of any other chemical compounds; thus EPA is considering only the potential risks of myclobutanil in its aggregate exposure assessment.

Determination of Safety for U.S. Population

Reference Dose (RfD): Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, EPA has calculated that aggregate exposure to myclobutanil will utilize 13.5% percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to myclobutanil residues

Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

From the rat developmental study, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (pup) NOEL was 93.8 mg/kg/day, based on increased incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day. From the rabbit developmental study, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (pup) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LEL of 200 mg/kg/day.

From the rat reproduction study, the maternal (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LEL of 50 mg/kg/day. The reproductive (parental) NOEL was 10 mg/kg/day, based on increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on current toxicological data requirements, the database for myclobutanil relative to pre- and post-natal toxicity is complete. The Agency notes that there is approximately a 25-fold difference between the developmental NOEL of 60 mg/kg/day from the rabbit developmental toxicity study and the NOEL of 2.5 mg/kg/day from the chronic rat feeding study which was the basis of the RfD. It is further noted that in both the rabbit and rat developmental toxicity studies, the developmental NOEL and maternal NOEL are the same (60 mg/kg/day for the rabbit and 93.8 mg/kg/day for the rat). In the rat reproduction study, the maternal NOEL (2.5 mg/kg/day) was four times lower than the developmental (pup) and reproductive NOELs (10 mg/kg/day). These studies indicate that there does not appear to be additional sensitivity for infants and children in the absence of maternal toxicity.

Reference Dose (RfD): Using the conservative exposure assumptions described above, EPA has calculated that the percent of the RfD that will be utilized by aggregate exposure to residues of myclobutanil ranges from 21.8 percent for children 7-12 years old, up to 73.1 percent for non-nursing infants. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

Other Considerations

The metabolism of myclobutanil in plants and animals is adequately understood for the purposes of these tolerances. There are no Codex maximum residue levels established for residues of myclobutanil on cucurbits. There is a practical analytical method for detecting and measuring levels of myclobutanil in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703-305-5805.